K073539

JAN 31 2008

510(K) SUBMISSION

SUMMARY:

PROVISA CEM is a dental cement and is particularly intended for the cementation of temporary crowns and bridges. Such a temporary prosthesis is a necessity for the patient in the period between the preparation of the tooth (or teeth) stump, followed by the impression taking, and the placement and cementation of the final prosthesis. During this period of one week or more, the prepared tooth stump has to be protected against any damage. But also the occlusal relationship of the tooth stump versus neighbouring and antagonist teeth has to be kept unchanged in order to prevent articulation problems upon placing the final prosthesis.

A temporary cement should offer sufficient retentive force to keep the temporary prosthesis in situ during the intervening week(s), but at the same time it should enable the dentist to take the prosthesis off without damaging the tooth stump and with no discomfort for the patient.

A variety of cement types is available for the dentist to cement the final prosthesis onto the tooth stump, many of which having a composite resin as their basic ingredient. PROVISA CEM is therefore free of eugenol, that used to be a component of many temporary cements. Eugenol, even in traces left behind on the tooth stump after removal of the temporary prosthesis, strongly inhibits the polymerisation reaction of a composite resin cement.

PROVISA CEM is presented in the form of two pastes: a white paste, containing zinc- and magnesium oxide as the reactive components and a yellow paste, containing fatty acid dimer as the reactive component. Upon mixing homogeneously, controlled by a uniform light yellow colour, a smooth paste with the correct consistency is formed, that can be pressed into a thin, but sufficiently strong cement layer.
Through a reaction between the metallic oxides and the fatty acid dimer, a chelate-network is formed, that makes the paste harden. The resulting cement is stable and strong enough but not too strong.

PROVISA CEM as a dental cement is exclusively handled by trained professional users.

Product Code: EMA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2008

Mr. Richard Woortman
Manager, Technical Services
Cavex Holland B.V.
Harmenjansweg 19
P.O. Box 852
2003 RW Haarlem
THE NETHERLANDS

Re: K073539
Trade/Device Name: PROVISA CEM
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: I
Product Code: EMB
Dated: December 15, 2007
Received: December 17, 2007

Dear Mr. Woortman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K073539

DEVICE NAME: PROVISA CEM

INDICATIONS FOR USE:

PROVISA CEM is intended for the cementation of temporary crowns and bridges. PROVISA CEM is free of eugenol. After its removal, it will also not inhibit the polymerisation of a composite cement or composite filling material.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073539